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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,768	12/30/1999	PINAKI RAY	03764.P002	6849

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EXAMINER

SERKE, CATHERINE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,768

Applicant(s)

RAY, PINAKI

Examiner

Catherine Serke

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 14-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 48-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sweezer et al.

Sweezer discloses a catheter system and method for providing cardiopulmonary bypass pump support during heart surgery that includes a delivery conduit (19) with an occlusion balloon (27), a collection conduit (1) with an occlusion balloon (6), a driving force (33) in communication with the delivery conduit, and an inflation/deflation control mechanism (43). The balloons are contractable. The perfusion fluid includes cardioplegia solution (chemotherapeutic chemicals).

Claims 3-4, 9 and 11 contain language regarding the functioning of the instant invention. The device as taught by Sweezer is capable of performing the recited functions. Specifically, the delivery conduit is capable of administering fluid during a substantial period of diastole or systole. The inflation/deflation control mechanism is capable of expanding the balloon during diastole and contracting the balloons during systole. The delivery conduit is capable of being positioned in the aorta and the collection conduit is capable of being positioned in the coronary sinus.

Claims 48-51, 53-56 and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Glickman (US Pat#5,817,046).

Glickman discloses a system for fluid isolation in a biological mass having an upstream channel and a downstream channel. The system includes a delivery occlusion conduit (3 or 4) that is positioned adjacent the upstream channel, a collection conduit (9) with at least one balloon that is positioned adjacent the downstream channel (see figure 1). The perfusion fluid is pumped (21) (pressure device) through the delivery conduit and reclaimed by the collection conduit (see spec 14:25-27). The fluid may be a chemotherapeutic agent. The collection conduit has at least three lumens that are used for fluid collection, a guidewire and balloon inflation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glickman.

Glickman meets the claim limitations as described above but fails to include the occlusion mechanism of the aortic occlusion catheter being a balloon and the catheter having three lumens.

At the time of the invention, it would have been obvious to incorporate a balloon as the method of occlusion for the aortic occlusion catheter since balloons are well known in the

Art Unit: 3763

catheter art to effectively, less-invasively and safely occlude blood vessels. The motivation for making the incorporation would have been in order to provide an occluding device that enhanced the safety to the patient by using a less invasive mechanism.

At the time of the invention, it would have been obvious to incorporate two additional lumens into the aortic occlusion catheter since the reference itself teaches a multi-lumen catheter (i.e. the collection conduit (9)) that has fluid, guidewire and inflation lumens. Having these three lumens in one catheter is common in the art since a balloon catheter if being used to transfer fluids will necessitate at least two lumens (i.e. one for fluid and one to inflate the balloon). Additionally, the procedure of using a guidewire to introduce a catheter into the body is also well known in the art and standard practice to ensure proper and safe placement of the device. The motivation for incorporating an inflation lumen and a guidewire lumen would have been to enable the use of a balloon (see paragraph above) and a guidewire thereby providing a device that has been enhanced for safety of the patient during placement and use.

Response to Arguments

Applicant's arguments filed 5/24/02 have been fully considered but they are not persuasive.

In response to applicant's argument that the prior art does not teach a collecting conduit for acquiring the fluid, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making,

Art Unit: 3763

the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.


Application/Control Number: 09/475,768

Page 6

Art Unit: 3763

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke 
August 22, 2002


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

8/23/02